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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,960	12/20/2000	Andres Metspalu	18056/00301	7252

2292 7590 08/27/2004

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

3M  
**Office Action Summary**

Application No.

09/741,960

Applicant(s)

METSPALU ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-49 is/are pending in the application.
- 4a) Of the above claim(s) 47-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claims 47-49 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Said claims 47-49 are directed to a method of analyzing nucleic acids, classified in class 435, subclass 91.1. This is distinct from claims 36-46, which are drawn to a device, classified in class 435, 287.2.

2. Inventions of claims 47-49 and of claims 36-46 are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device as claimed can be used in a materially different process such as one involving immunological binding, classified in class 435, subclass 7.1.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 47-49 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

For convenience, claim 36, the sole independent claim under consideration, is reproduced below.

Claim 36. (New) A device for the analysis of biological molecules linked to a fluorophore, comprising:

a light source emitting at least one laser beam directed into a waveguide support, said waveguide support supporting total internal reflection and comprising a top surface, a bottom surface and at least one edge surface, wherein said biological molecules are affixed to said top surface;

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means for directing said at least one laser beam into said edge of said waveguide support; and

a charge couple device for detecting emission spectra of said biological molecules,

wherein said waveguide support is spatially situated between said light source and said charge couple device.

6. For purposes of examination, said claim has been interpreted as encompassing the simultaneous detection of a plurality of spectrally different emissions from biological molecules where the biological molecules do not have any added detectable moiety, fluorescent or otherwise. Said claimed device has also been interpreted as comprising but a single laser that is in turn used to cause the biological molecules to elicit said emission. Said claim has also been interpreted and

7. In accordance with claim 46, the device is to be used with "the Arrayed Primer Extension (APEX) assay." The specification is essentially silent as to how this method is to practiced. While page 3 of the disclosure provides literal support for this embodiment, the specification does not set forth any reaction conditions or starting materials as to how this critical aspect is to be practiced, much less describe in such full, clear, and concise terms how the laser is used in this procedure as compared to other embodiments. Indeed, the specification fails to disclose any example where any biological molecule is arrayed and detected by the claimed device.

8. In accordance with claim 39, a cylindrical lens is to be "moving perpendicular to the plane of said at least one laser beam," however, the disclosure does not provide any description of the means used to effect such motion, much less how such motion would be controlled. Upon review of Figure 5 it is plainly evident that the "cylindrical lens" does not move perpendicular to

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the laser beam, but rather, revolves around an axis approximating said laser beam. A wedge-shaped lens, however, is depicted as being capable of moving perpendicular to the laser beam. Such depictions are in stark contrast with the description provided at page 5 and as presented in new claims 38 and 39. In any event, the depictions and the description do not describe how any one element is caused to move.

9. In accordance with claim 43, the device is to comprise "transparent liquid located between said waveguide support and said optical prism, which possesses a refractive index about equal to the refractive indices possessed by said waveguide support and said optical prism." A review of the disclosure fails to find an adequate written description of just which liquids are suitable for use in conjunction with the elements of the device and which allow for practicing the detection of the biological molecules.

10. Rather than teach in such full, clear, and concise terms what the claimed invention is, and how it is to be made and used, it appears that applicant is attempting to rely upon obviousness in order to satisfy the written description requirements of 35 USC 112, first paragraph. Indeed, applicant appears to be relying upon obviousness to teach the APEX method. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

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11. In view of the foregoing remarks and in the absence of convincing evidence to the contrary, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing. Accordingly, claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

*New Matter*

12. As presently worded, the device of claims 36-46 is to result in the detection of any biological molecule as a result of "detecting emission spectra of aid biological molecules." A review of the specification fails to find support for such a limitation. The specification does teach fluorescently labeled nucleotides that have been added to primers in a primer extension reaction. No other label is described. Furthermore, the record is silent as to there being any detectable emission from unlabeled biological molecules. Therefore, and in the absence of convincing evidence to the contrary, claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

13. Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513

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(Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

14. As presented above, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing. It is well settled that one cannot enable that which they do not yet possess. Accordingly, and in the absence of convincing evidence to the contrary, claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

15. In accordance with the claims, the device is to comprise elements that are to result in the detection of any biological molecule whereby said biological molecules are detected through their "emission spectra." The specification is silent as to how any biological molecule is detected through their inherent emission spectra; *supra*.

16. In accordance with claim 43, one is to result in a device that comprises a "transparent liquid located between said waveguide support and said optical prism, which possesses a refractive index about equal to the refractive indices possessed by said waveguide support and



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said optical prism." The specification is essentially silent as to which combinations of supports and transparent liquids are suitable, much less teach in such full, clear, and concise terms as to how any assay is to be conducted, including the arguable preferred embodiment of APEX.

The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001.

As set forth in the decision of the Court:

" '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher*, 427 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

\*\*\*\*\*

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'). Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

"It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

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17. The art to which the invention relates, i.e., nucleic acid array art and hybridization art, has advanced to the point that certain problematic areas have been identified. In support of this position as it relates to the manufacture and use of oligonucleotide arrays, US Patent 6,077,674 (Schleifer et al.) addresses certain highly problematic areas:

While in situ synthesis is a very flexible means for producing DNA arrays, the fidelity or percentage of full-length oligonucleotides synthesized within a feature on the array is less than 100 percent. An ideal array will have only full-length oligonucleotides attached to each feature. The ideal array promotes accuracy in hybridization experiments or assays or target biological materials. If the fidelity of an in situ generated array is less than 100 percent, it typically has non full-length oligonucleotides within a feature that usually consists of shorter lengths of the correct sequence, and to a lesser degree, incorrect sequences. Typical DNA coupling efficiencies are around 97 to 99 percent for the standard phosphoramidite chemistry. For oligonucleotides that are 25 nucleotides in length, these efficiencies result in only 46 to 77 percent full-length oligonucleotides contained within a feature ( $0.97^{25}$  to  $0.99^{25}$ ). This loss of fidelity can cause chemical noise in hybridization conditions. The loss of fidelity can also lead to difficulty in interpreting the data.

Photolithography is a method used by Affymetrix in California to produce in situ arrays using procedures that are similar to those used in the semi-conductor industry. In procedure described by Fodor et al. from Affymetrix U.S. Pat. No. 5,405,783, a photo-deprotection step is used where the protecting group on the phosphoramidite is removed by exposing a photosensitive protecting group to light. Four photo masks are used to create patterns to de-protect areas of the substrate and then a nucleotide is added to these regions. This technique requires four masks for each layer of nucleotides. While this technique allows for the production of high-density oligonucleotide arrays, it is less efficient than traditional phosphoramidite synthesis chemistry. With efficiencies of about 90 to 95 percent, the percentage of full-length oligonucleotides within a feature is further reduced to about 9 to 27 percent for oligonucleotides that are 25 nucleotides long ( $0.90^{25}$  to  $0.95^{25}$ ).

18. Carrico, (US Patent 5,200,313) similarly identifies problematic aspects of hybridization reactions:

1. The purity of the nucleic acid preparation.

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2. Base compositions of the probe - G-C base pairs will exhibit greater thermal stability than A-T or A-U base pairs. Thus, hybridizations involving higher G-C content will be stable at higher temperatures.

3. Length of homologous base sequences- Any short sequence of bases (e.g., less than 6 bases), has a high degree of probability of being present in many nucleic acids. Thus, little or no specificity can be attained in hybridizations involving such short sequences. From a practical standpoint, a homologous probe sequence will often be between 300 and 1000 nucleotides.

4. Ionic strength- The rate of reannealing increases as the ionic strength of the incubation solution increases. Thermal stability of hybrids also increases.

5. Incubation temperature- Optimal reannealing occurs at a temperature about 25 - 30 °C below the melting temperature for a given duplex. Incubation at temperatures significantly below the optimum allows less related base sequences to hybridize.

6. Nucleic acid concentration and incubation time- Normally, to drive the reaction towards hybridization, one of the hybridizable sample nucleic acid or probe nucleic acid will be present in excess, usually 100 fold excess or greater.

7. Denaturing reagents- The presence of hydrogen bond-disrupting agents, such as formaldehyde and urea, increases the stringency of hybridization.

8. Incubation- The longer the incubation time, the more complete will be the hybridization.

9. Volume exclusion agents- The presence of these agents, as exemplified by dextran and dextran sulfate, are thought to increase the effective concentrations of the hybridizing elements thereby increasing the rate of resulting hybridizations.

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Further, subjecting the resultant hybridization product to repeated washes or rinses in heated solutions will remove non-hybridized probe. The use of solutions of decreasing ionic strength, and increasing temperature, e.g., 0.1X SSC for 30 minutes at 65 °C, will, with increasing effectiveness, remove non-fully complementary hybridization products.

The specification is silent as to how these art-recognized issues are to be overcome when practicing the claimed invention.

19. For the above reasons, and in the absence of convincing evidence to the contrary, claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

20. At pages 5-7 of the response filed 12 May 2003 argument is presented against the prior rejection of claims 18-21, 23-27, and 30-31. While the cancellation of said claims has rendered moot said rejection, the arguments are addressed below to the extent that they are applicable to the presently rejected claims, i.e., claims 36-46.

21. Agreement is reached in that an applicant is not required to disclose that which is well known. However, to not set forth any reaction conditions or essential starting materials for the manufacture and ultimate use of the claimed device does not satisfy enablement of method of making and using the allegedly novel and non-obvious invention. *Genentech*.

22. Argument is presented that APEX is disclosed in US Patent 6,153,379. While APEX may well be disclosed in said document, the patent did not issue until 28 November 2000, which is more than a year subsequent to the effective filing date of the instant application.

Accordingly, it was not available, and the instant disclosure does not incorporate such material

by reference. Therefore, and in the absence of convincing evidence to the contrary, the rejection is applied/maintained to the new claims.

23. Argument is presented that the publications of Kurg et al., and Tōnisson et al., also disclose APEX. In support of this position, applicant has furnished the Office with copies of said publications. Upon inspection of Kurg et al., it is noted that the article has a publication date of 2000. The publication of Tōnisson et al., has a publication date of April 16, 2002. In both cases, the documents were published subsequent to the effective filing date of the instant application, which is 21 April 1999. Accordingly, the record does not demonstrate that APEX was known in the art, much less be well known in the art at the time of filing.

24. At page 7 of the response of 12 May 2003 argument is presented that the problems identified in US Patent 5,200,313 (Carrico) are not applicable to the claimed invention as the device is to be used in an APEX assay.

25. The above argument has been fully considered and has not been found persuasive. While claim 43 makes reference to the arrangement of the elements of the claimed device such that APX can be performed, such does not limit or proscribe the claimed device from being used in a hybridization assay. Indeed, even the aspect of performing APEX still requires a primer to hybridize to a target nucleic acid. Accordingly, the art-recognized issues identified by Carrico are relevant and the instant disclosure is essentially silent as to how any of these issues is to be overcome. Therefore, and in the absence of convincing evidence to the contrary, claims 36-46 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

***Declaration of Lewis T. Claiborne under 37 CFR 1.132 (filed 04 September 2001)***

26. In the response of 12 May 2003 applicant has made repeated referenced to the above declaration in the context of traversing rejections of claims under 35 USC 112, second paragraph. While no claims are presently rejected under 35 USC 112, second paragraph, the value of the declaration in terms of overcoming issues of enablement is addressed below.
27. At page 1, bridging to page 2 of the declaration Declarant Claiborne stipulates that he has 38 years of industrial research and has "invented and developed numerous instruments and applications based on optical principles." The declaration was also found to contain the *curriculum vitae* of the three applicants. Upon inspection of the *c.v.* of the applicant, it is readily apparent that declarant has more years of industrial research than all three inventors combined. In view of the vast years of experience, and the awarding of no less than four patents over four years (US Patent 6,452,187, US Patent 6,359,596, US Patent 6,180,990, and US Patent 6,054,718), declarant is not considered to be a person of skill in the art (declaration at page 3, paragraph 7), but rather, a person of exceptionally high skill in the art.
28. At page 4 of the declaration declarant stipulates:
- "I am an independent consultant with no relationship, personal or monetary, with any applicant or inventor U.S. Patent Application 09/741,960 entitled METHOD AND DEVICE FOR IMAGING AND ANALYSIS OF BIOPOLYMERARRAYS." A review of the declaration fails to locate where declarant identifies that in providing the declaration to the then applicant's counsel, the firm of SIDLEY AUSTIN BROWN & WOOD LLP, that declarant was also providing this service to the same firm that had successfully prosecuted his US Patent Application 09/277,694, which issued as US Patent 6,180,990, and which declarant refers to at

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page 2, first paragraph, of the instant declaration. Accordingly, the statements proffered are not considered to be those of a disinterested third party.

29. While declarant asserts that the invention is not unpredictable (paragraph 7), and can be practiced without undue experimentation (paragraph 4), such statements are conclusory. While declarant acknowledges the *Wands* factors (declaration at paragraph 5), the declaration is essentially silent as to how each, or even any of these specific elements are satisfied at any specific location (page(s)) of the instant disclosure. Further, not evidentiary showing is made for any purpose.

30. In view of the exceptionally high level of skill of declarant and the absence of any evidentiary showing that supports the conclusions proffered, the declaration has not been found persuasive towards concluding that the claims are fully enabled by the instant disclosure.

31. For the above reasons, and in the absence of convincing evidence to the contrary, claims 36-46 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

### *Conclusion*

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR



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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script, reading "B. L. Sisson".

Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
24 August 2004